

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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POLICY

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GOI Invites Comments on Fortified Foods Regulation

Report Categories:

Sanitary/Phytosanitary/Food Safety

Exporter Guide

FAIRS Subject Report

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Report Highlights:

India has invited World Trade Organization (WTO) members to provide comments on its draft amendments related to standards, mainly for fortified processed foods, multi-grain *atta* (flour) and fortified milk. The comment period for trading partners expire on April 30, 2019, per WTO notification number [G/SPS/N/IND/232](#).

General Information:

DISCLAIMER: The information contained in this report was retrieved from the Food Safety and Standard Authority of India's (FSSAI) website <http://www.fssai.gov.in/>. The Office of Agricultural Affairs, USDA and/or the U.S. Government make no claim of accuracy or authenticity.

On February 19, 2019, FSSAI published the Food Safety and Standards (Fortification of Foods) Amendment Regulations, 2019 relating to proposed changes mainly in the standards for fortified processed foods, multi-grain *atta* (flour) and fortified milk. These amendments will come into force on the date of their final publication in the Official Gazette of India.

Readers may note the major amendments listed below. However, it is advisable to refer to the FSSAI notification for the complete amendments. The full text of the notification is pasted at the end of this report and also available on the FSSAI's website <http://www.fssai.gov.in/>.

- 1) A new clause inserted in Regulation 2, sub-regulation (1) after clause (d), to read as:
“(da) “Fortified Processed Foods” means foods that have been altered from its natural state by industrial processing methods. The same may have fortified staples as raw materials and/or fortified with permitted micronutrients and additives as specified under the Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011.”
- 2) New clauses inserted in Regulation 3, sub-regulation (1) after clause (e), to read as:
“(f) Fortified Processed Foods may be prepared from fortified food articles that may be cereals and/or milk;
(g) The Fortified Processed Food shall provide 15-30% of the Indian adult RDA of micronutrients based on an average calorie intake of 600 Kcal from processed foods (~1/3 of energy of 2000 kcal);
(h) High Fat Sugar Salt (HFSS) Foods shall be excluded from the Fortified Processed Foods category.”
- 3) A sub-regulation (2) added in Regulation 4, to read as:
“(2) Any manufacturer who fortifies any processed food shall ensure that the level of micronutrients in such fortified processed food does not fall below the minimum level specified in Schedule-III.”
- 4) A new proviso added to Regulation 7, after sub-regulation (2), to read as:
“Provided that the requirements as specified in sub-regulation (2) is not required in case of iodized salt (when fortified with iodine).”
- 5) In schedule-I, amendments made to clause (3) on “fortified milk”. Readers may refer to the notification to know the details. In clause (4) after the second table, the following has been inserted:
“Multi-grain *atta* (flour) may also be fortified with vitamins and minerals at the same levels specified for ‘Fortified Atta’ provided that the multi grain *atta* (flour) contains more than 50% as wheat flour in it.”

- 6) A new 'SCHEDULE-III' has been inserted after Schedule-II which provides the level of fortified nutrients per 100 kcal for fortified cereal products, bakery wares and fruit juices.

Comments should be sent by April 30, 2019 to spstbt.enqpt@fssai.gov.in.

Details of Notification:

- Date of Publication on FSSAI website: February 19, 2019
- Date of Publication on WTO website: March 1, 2019
- Final date for comments from WTO members: April 30, 2019

Agency in Charge: Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, GOI.

Products affected: fortified food products

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 4th February, 2019

F. No. REG/Fortification Amendment (1)/Notification/FSSAI-2018.— The following draft of certain regulations further to amend the Food Safety and Standards (Fortification of Foods) Regulations, 2018, which the Food Safety and Standards Authority of India proposes to make, with the previous approval of the Central Government in exercise of powers conferred by clause (e) of sub-section (2) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006) is hereby published as required by the said sub-section (1) of section 92, for the information of persons likely to be affected thereby and notice is hereby given that the said draft regulations will be taken into consideration after expiry of a period of thirty days from the date on which the copies of the Official Gazette in which this notification is published are made available to the public;

Objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi-110002, or may be sent at regulation@fssai.gov.in:

The objection or suggestion which may be received from any person with respect to said draft regulations, before the expiry of the period specified above, will be considered by the Food Authority.

Draft Regulations

1. **Short title and commencement.-** (1) These regulations may be called the Food Safety and Standards (Fortification of Foods) Amendment Regulations, 2019.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Food Safety and Standards (Fortification of Foods) Regulations, 2018 (herein after referred as said regulation)-

(A) In regulation 2, in sub regulation (1), after clause (d), the following clause shall be inserted, namely:-

“(da) **“Fortified Processed Foods”** means foods that have been altered from its natural state by industrial processing methods. The same may have fortified staples as raw materials and/or fortified with permitted micronutrients and additives as specified under the Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011.”

(B) in regulation 3, in sub-regulation (1), after clause (e), the following clauses shall be inserted, namely:-

“(f) Fortified Processed Foods may be prepared from fortified food articles that may be cereals and/or milk;

(g) The Fortified Processed Food shall provide 15-30% of the Indian adult RDA of micronutrient based on an average calorie intake of 600 kcal from processed foods (~1/3 of energy of 2000 kcal);

(h) High Fat Sugar Salt (HFSS) Foods shall be excluded from Fortified Processed Foods category.”

(C) in regulation 4, after sub-regulation (1), the following sub-regulation shall be inserted, namely:-

(2) Any manufacturer who fortifies any processed food shall ensure that the level of micronutrient in such fortified processed food does not fall below the minimum level specified in Schedule-III.

(D) in regulation 7, after sub-regulation (2), the following proviso shall be inserted, namely:-

Provided that the requirements as specified in sub-regulation (2) is not required in case of iodized salt (when fortified with iodine).

(E) in Schedule- I, -

(a) for clause (3), the following shall be substituted, namely:-

“3. Fortified Milk

Species identified Milk (namely buffalo milk, cow milk, goat milk, sheep milk and camel milk), full cream milk, Toned milk, double toned milk, skimmed milk and standardized milk shall be fortified with the following micronutrients at the level given in the table below, wherein the milk is to undergo the process of pasteurization, sterilization, Ultra High Temperature sterilization/treatment or boiling:

S. No.	Nutrients	Level of nutrient per litre of Species identified Milk (namely buffalo milk, cow milk, goat milk, sheep milk and camel milk)/ Full Cream Milk/Toned milk/double toned milk/skimmed milk/standardized milk	Source of nutrient
1.	Vitamin A	270 µg RE- 450 µg RE	Retinyl acetate or Retinyl palmitate
2.	Vitamin D	5 µg- 7.5 µg	*Cholecalciferol or*Ergocalciferol (*Only from Plant source)

Note: Vitamin A (retinol): 1 IU= 0.3 µg RE (Retinol Equivalent); Vitamin D (Cholecalciferol or Ergocalciferol): 1 IU= 0.025 µg”

(b) in clause (4), after the second table, following statement shall be inserted, namely :-

“Multi-grain Atta may also be fortified with vitamins and minerals at the same levels specified for ‘Fortified Atta’, provided that the multi grain atta contains more than 50% as wheat flour in it.”

(F) after Schedule –II, the following Schedule shall be inserted, namely:-

“SCHEDULE-III

STANDARDS FOR FORTIFIED PROCESSED FOODS

[See sub-regulation (2) of regulation 4]

1. Fortified Cereal Products¹:

(1) Cereal products include Breakfast cereals, Pasta and Noodles, when fortified, shall contain added iron, folic acid and Vitamin B-12 at the level given in the table below, namely:-

TABLE

S.No.	Nutrients/Source	Level of Fortification per 100 kcal
1	Iron (mg) Ferrous citrate or Ferrous lactate or Ferrous sulphate or Ferric pyrophosphate or electrolytic iron or Ferrous fumarate or Ferrous Bis Glycinate; or Sodium Iron (III) Ethylene diamine tetra Acetate Trihydrate (Sodium feredetate -Na Fe EDTA);	0.5-1.0
2	Folic acid (µg)	2.5 -5
3	Vitamin B12 (µg) - Cyanocobalamine, or Hydroxycobalamine;	0.025 -0.05

(2) In addition, Fortified Cereal products may also be fortified with following micronutrients, singly or in combination, at the level in the table below, namely:-

TABLE

S.No.	Nutrient/Source	Level of Fortification per 100 kcal
1.	Zinc (mg): Zinc Sulphate	0.3 -0.6
2.	Vitamin A (µg RE): Retinyl acetate or Retinyl Palmitate,	15 -30
3.	Thiamine (Vitamin B1) (mg): Thiamine hydrochloride or Thiamine mononitrate;	0.04-0.08
4.	Riboflavin (Vitamin B2) (mg): Riboflavin or Riboflavin 5'-phosphate sodium ;	0.04-0.08
5.	Niacin(Vitamin B3) (mg): Nicotinamide or Nicotinic acid;	0.05-1.0
6.	Pyridoxine (Vitamin B6) (mg): Pyridoxine hydrochloride;	0.05-0.1

¹Note: ‘Fortified Cereal Products’ shall not have Total Fat or Trans Fat or Added Sugar or Salt beyond the limit specified as under:

TABLE

(1)	Total Fat/100gm (2)	Trans Fat (3)	Added Sugar (4)	Sodium/100gm (5)
Fortified Breakfast Cereals	Not more than 12.0 gm	Not more than 1 per cent of total energy	Not more than 10 per cent of total energy	Not more than 0.35 gm
Fortified Pasta/Noodles	Not more than 3.0 gm			Not more than 0.25 gm

2. Fortified Bakery wares²:

(1) Bakery wares includes bread, biscuits, rusks and buns ,when fortified, shall contain added iron, folic acid and Vitamin B-12 at the level given in the table below, namely:—

TABLE

S.No.	Nutrients/Source	Level of Fortification per 100 kcal
1	Iron (mg): Ferrous citrate or Ferrous lactate or Ferrous sulphate or Ferric pyrophosphate or electrolytic iron or Ferrous fumarate or Ferrous BisGlycinate; or Sodium Iron (III) Ethylene diamine tetra Acetate Trihydrate (Sodium feredetate -Na Fe EDTA);	0.5-1.0
2	Folic acid (µg)	2.5 -5
3	Vitamin B12 (µg)- Cyanocobalamine, or Hydroxycobalamine;	0.025 -0.05

(2) In addition, Fortified Bakery wares may also be fortified with following micronutrients, singly or in combination, at the level in the table below:

TABLE

S.No.	Nutrient/Source	Level of Fortification per 100 kcal
1.	Zinc (mg): Zinc Sulphate	0.3 -0.6
2.	Vitamin A (µg RE): Retinyl acetate or Retinyl Palmitate,	15 -30
3.	Thiamine (Vitamin B1) (mg): Thiamine hydrochloride or Thiamine mononitrate;	0.04-0.08
4.	Riboflavin (Vitamin B2) (mg): Riboflavin or Riboflavin 5'-phosphate sodium ;	0.04-0.08
5.	Niacin(Vitamin B3) (mg): Nicotinamide or Nicotinic acid;	0.05-1.0
6.	Pyridoxine (Vitamin B6) (mg): Pyridoxine hydrochloride;	0.05-0.1

² **Note:** 'Fortified Bakery Wares' shall not have Total Fat or Trans Fat or Added Sugar beyond the limit specified under:

TABLE

(1)	Total Fat/100gm (2)	Trans Fat (3)	Added Sugar (4)	Sodium/100gm (5)
Fortified Bakery Wares	Not more than 8.0 gm	Not more than 1 per cent of total energy	Not more than 10 per cent of total energy	Not more than 0.25 gm

3. Fortified Fruit Juices³:

(1) Fruit juices, when fortified, shall contain Vitamin C at the level given in the table below:

TABLE

S. No.	Nutrient/Source	Level of Fortification per 250 m L
1.	Vitamin C (mg): Ascorbic acid	36 - 41

³**Note:** 'Fortified Fruit Juices' shall not have Total Fat or Trans Fat or Added Sugar or Salt beyond the limit specified as under:

TABLE

(1)	Total Fat/100gm (2)	Trans Fat (3)	Added Sugar (4)	Sodium/100gm (5)
Fortified Fruit Juices	No threshold	No threshold	Not more than 10 per cent of total energy	No threshold

PAWAN AGARWAL, Chief Executive Officer

[ADVT. III/4/Exty./521/18]

Note : The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 *vide* notification number F. No. 11/03/Reg/Fortification/2014, dated the 2st August, 2018.